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MEMORANDUM

TO: **EPA Office of Solid Waste**

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RE: Docket ID No. RCRA-2003-0012, Management of Hazardous Waste in Laboratories

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Background

The Commonwealth of Massachusetts is fortunate to host an economic cluster of a comprehensive life-sciences industry whereby the local biotechnology industry is intrinsically-linked to the world class educational and hospital organizations that reside here. With indistinct boundaries between them, these institutions provide a synergy of technical genius, business entrepreneurs, and research facilities that germinated the inception of the local biotechnology industry as a grass roots, organic effort. Originating from physicians, professors, and principal investigators that formed business ventures to pursue their ideas, the Greater Boston life sciences industry has evolved into a worldwide magnet for innovative biotechnology research and product development. The kernel that binds them all are laboratory operations within which basic research tests an hypothesis and formulates a more complete understanding and solution by way of the scientific process.

Statement of the Problem

The current RCRA regulatory framework, crafted with heavy industrial applications in mind, is antithetical to laboratory operations common to higher education, healthcare, and biotechnology institutions. The regulations do not fit well for operations that deal with small volumes of a large number of hazardous wastestreams that are decentralized and distributed throughout a facility or a campus. The basic production unit in a research, clinical, or academic laboratory setting is a fume hood that provides a shared work environment, usually for one person at a time. A few to many fume hoods may be situated within each laboratory. Recent EPA enforcement actions stemming from inspections of laboratory operations have resulted in large penalties for cumulative minor infractions of how small volumes of hazardous waste have been managed within fume hoods and with movement to central accumulation areas for offsite disposal, among other adverse RCRA-related findings.

The functionality of laboratories has been compromised by the RCRA regulations without significant net social benefit in return. Laboratories in the life-sciences industry perform the function of learning and training to promote knowledge, providing healthcare to reduce suffering, and developing new medicines and cures to prevent disease. Therefore, regulatory change is necessary to implement common sense requirements that adequately protect human health and the environment more in balance with the social benefits derived from laboratories.

Practical Regulations Developed for Industrial Facilities

With its industrial focus and insight, certain existing RCRA regulatory conditions provide some flexibility to operations with high volumes of a small number of wastestreams in select locations common to production or manufacturing environments. An important example of a common sense approach to management of hazardous waste in industrial settings involving the concept of "*Totally enclosed treatment facility*" as defined in 40 CFR 260.10. This approach provides for "treatment of hazardous waste which is directly connected to an industrial process and which is constructed and operated in a manner which prevents the release of any hazardous waste or any constituent thereof into the environment during treatment." The term is applied in 40 CFR 261.5(c)(2) when making quantity determinations for conditionally exempt small quantity (CESQ) generators where hazardous waste are excepted when it "is managed immediately upon generation only in on-site elementary neutralizations units, wastewater treatment units, wastewater treatment units, or *totally enclosed treatment facilities*." It again appears in 40 CFR 264.1(g)(5) to exempt facilities from licensing requirements as a treatment operation for "the owner or operator of a *totally enclosed treatment facility*."

The Commonwealth of Massachusetts is known for having hazardous waste regulations that are not only more stringent that those of the EPA but are perhaps the most restrictive in the country. A case in point is the prohibition of treatment in accumulation containers by state statute. However, based upon the concept of *totally enclosed treatment facility*, the Commonwealth has developed the definition of "*treatment which is an integral part of the manufacturing process.*" As defined in the Hazardous Waste Regulations, 360 CMR 30.010, the definition refers to "….any treatment method or technique which is at the site of generation of the waste …. and totally enclosed so that it is designed, constructed, and operated to prevent spills, leaks, or emissions of hazardous materials to the environment."

Application of Analogous Regulations to Laboratory Operations

My recommendation is to extend and modify the concept of *totally enclosed treatment facility* to apply to fume hoods as used by laboratory operations. The modification acknowledges that fumes hoods are not totally enclosed in the same sense as a manufacturing production unit. In fact, fume hoods are designed to protect laboratory technicians and minimizing exposure in the workspace by emitting and releasing gases into the atmosphere, usually without further treatment or absorption of hazardous materials.

Due to the extremely small quantities of chemicals used in a fume hood, the cumulative emissions of volatile or gaseous material released from fume hoods have insignificant impact on air quality and do not approach the regulatory thresholds of air emission regulation that are measured in tons per year. Volatile chemicals are normally used in milliliter quantities, certainly less than a liter at a time. Note that fume hoods are commonly used vent 100s of milliliters of organics solvents such as methylene chloride as part of standard laboratory procedures. These procedures include rotary evaporation and Kuderna-Danish concentration of semi-volatile organic compounds as sample preparation techniques required by EPA in Method 3500 of SW-846. Despite widespread application of these techniques in large-volume production environmental laboratories, by themselves, these emissions rarely exceed thresholds for air permitting where emission rates are measured in units of tons of solvent emitted per year. The application of similar techniques in other laboratory settings represent a source of emissions that greatly exceed the rate of release that should be expected with the normal handling of volatile materials as managed as waste; either for local accumulation or potential treatment. Therefore, if emissions from commercial or pedagogic activities are tolerable, then the lower rate of emission that can be expected from treatment and handling of materials before and after they become a waste should also not be viewed as an added detriment to air quality.

Benefits of Considering Fume Hoods as a *"Totally enclosed treatment facility"*

Fume hoods are designed to protect human health and the environment from potentially harmful activities conducted in research, clinical, and academic laboratories. Considering fume hoods as a *totally enclosed treatment facility* provides a practicable means for providing regulatory relief and streamlining that could have significant positive effect on laboratory operations. This approach will also enhance protection of human health and the environment as an improvement over current practice by the following mechanisms:

- Standard laboratory procedures and experiments could be amended to include techniques for neutralizing, stabilizing, or detoxifying small amounts of hazardous materials at the source, before a waste has been technically generated.

- The generator, who frequently has the most knowledge of the potential hazards of a material, could build in the opportunity to render the material non-hazardous as part of the experiment or procedure (i.e., *integral to the process*) within a safe working environment (i.e., the fume hood serving as the *totally enclosed treatment facility*).

- Hazardous materials would then be treated as they arise and not accumulated over time into larger volumes that present a greater risk. Therefore, the smallest quantities of hazardous material could be treated without internal transport at the point of generation for a net safety benefit.

- By minimizing satellite accumulation, the need to move hazardous wastes internally within a facility to a central accumulation area could also be diminished.

- Direct treatment at the source minimizes the need for lab pack of laboratory wastes in a collection of small, sealed containers into drums for off-site disposal and treatment. This could eliminate the possibility of inadvertent disposal of incompatible materials together that could co-mingle and react upon spillage or breakage.

- The expansion of treatment in laboratory settings could result in a reduction of off-site disposal and relieve a burden on the manifest tracking system for accounting for lab pack drums and other waste streams. (It is conceded that certain forms of treatment could actually result in a net increase in waste volume and the treated material still subject to regulation as hazardous waste.)

- By treating and eliminating hazardous waste at the source before a procedure has been completed, the waste has technically not been generated. Therefore a permit should not be needed, as in the analogous case with treatment within manufacturing process operations in *totally enclosed treatment systems* that is *integral to the process.*

- Abuse of the treatment technique, for example by venting open containers of volatile organic solvents as a means of disposal, can be anticipated and should be controlled by maintaining existing specific regulatory prohibitions for this improper activity.

Postponement of Hazardous Waste Determination

A significant agenda item of the June 18 teleconference was "*When should the hazardous waste determination be made in a laboratory setting?*" By deferring the determination to another location away from the point of generation, the timing of the determination is necessarily postponed to some point in time after the time of generation. A forceful argument has been made that other facilities than the fume hood where the material originated may be better equipped to perform a determination, and that other facility personnel, such as experienced environmental, health, and safety professionals, may be better trained to perform the determination.

Unless applying generator knowledge of the material, the material is technically not a hazardous waste until a formal determination has been performed. This creates an additional opportunity for treatment without a license that would realize many of the same benefits proposed above for treatment within a fume hood as integral to the laboratory process within a closed system. This approach provides flexibility for assigning the place and personnel to conduct treatment activities in the safest possible manner with improved protection to the environment by eliminating the hazardous quality of a material without leaving a confined facility.

Conclusion

It is widely accepted by the regulatory, laboratory, and stakeholder communities that current RCRA regulations do not apply well to the laboratory environment and create operational issues detrimental the purposes and functionality of a laboratory. The current regulatory framework is not efficient in protecting social interests in terms of public safety and environmental protection as it encourages extensive handling and transport of hazardous materials away from the point of origin. Application of process concepts that allow for treatment of hazardous materials similar to those currently in place for industrial settings would significantly streamline hazardous waste management in laboratory settings. Fume hoods provide a suitable setting for safe and confined waste treatment analogous to that provided by a totally enclosed industrial process unit. Postponement of determination offers other means to accommodate treatment removed from the point of generation. Performance-based regulations for treatment of small volumes of a variety of substances originating from laboratory operations offer superior protection of human health and environmental quality than existing regulations that do not distinguish between the very different realities of laboratory and industrial activities.

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